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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,594	12/28/2004	David Cavalla	GJE-6758	2624

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EXAMINER

SOROUGH, LAYLA

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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12/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/519,594	Applicant(s) CAVALLA ET AL.	
	Examiner Layla Soroush	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed September 20, 2007 presents remarks and arguments submitted to the office action mailed May 31, 2007 is acknowledged.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 1-7 over Ninomiya et al. (US Pat. No. 4,695,568 –IDS), in view of McInally et al. (PCT/SE98/00641 English equivalent US Pat. No. 6303613) is persuasive. Therefore, the rejection is withdrawn.

Applicant's arguments over the 35 U.S.C. 101 rejection of claims 1-7 over co-pending Application No. 10/617847 is not persuasive. The ODP rejection will be withdrawn upon the filing and approval of the Terminal Disclaimer.

In view of applicant's arguments to the claims, the following new rejections are made:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (Effects of Acute and Chronic Administration of MCI-225, a New Selective Noradrenaline Reuptake Inhibitor With 5-HT₃ Receptor Blocking Action, on Extracellular Noradrenaline Levels in the Hypothalamus of Stressed Rats. Japan. Journal of

Pharmacology.83.pages 31-38.200) and Ninomiya et al. (US Pat. No. 4,695,568—previously presented) in view of Davies et al. (US Pat. No. 6,008,227—previously presented).

Wu et al. teaches (4-(2-fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-D]pyrimidine hydrochloride monohydrate (MCI-225) is a psychoactive compound that is a selective noradrenaline (norepinephrine) reuptake inhibitor with 5-HT₃ receptor blocking action which has been reported to have antidepressant activity.

Ninomiya et al. is solely used to show that the general teaching of administration of the (4-(2-fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-D]pyrimidine hydrochloride monohydrate to a patient renders obvious the administration to both male and female patients. Hence, meeting the limitation of claim 5.

Wu et al. does not specifically teach the compound to treat irritable bowel syndrome.

However, Davies et al. teaches, in the Background of the Invention, that two important central nervous system neurotransmitters are serotonin (5-HT) and dopamine (DA). Together with norepinephrine and epinephrine, these neurotransmitters comprise the group of agents known as the monoamines. Either 5-HT or DA have been implicated in a variety of disorders, including depression, Parkinsons disease, ADD, obesity and cocaine addiction. Antidepressants inhibit monoamine uptake mechanisms, but differ in selectivity between the dopamine, 5-HT and norepinephrine transporters. Other syndromes also respond to antidepressant drugs. These include (1) severe

anxiety syndromes characterized by panic reactions, and (2) obsessive-compulsive disorder, both of which seem most likely to respond to 5-HT selective agents.

Monoamine uptake blockers have also been useful in treatment of chronic pain, neuralgias, migraine, sleep apnea, fibromyalgia, and irritable bowel syndrome (functional bowel disorder) (column 1 lines 60-67 and column 2 lines 1-2).

Therefore, it would have been obvious to one of ordinary skill in the art to use a psychoactive compound that is a selective noradrenaline (norepinephrine) reuptake inhibitor with 5-HT₃ receptor blocking action which has been reported to have antidepressant activity in treating irritable bowel syndrome. The motivation to use 4-(2-Fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-D]pyrimidine to treat irritable bowel syndrome is because the teachings in Davies et al. that antidepressant agent used to inhibit monoamine uptake mechanisms are also useful in treating chronic pain, neuralgias, migraine, sleep apnea, fibromyalgia, and irritable bowel syndrome (functional bowel disorder). The skilled artisan would have reasonable expectation of treating the irritable bowel syndrome (functional bowel disorder) using the antidepressant drug 4-(2-Fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-D]pyrimidine.

Additionally, because the reference teaches the genus irritable bowel syndrome, the species constipation -predominant irritable bowel syndrome, and alternating constipation/diarrhea of claims 6 and 7 are rendered obvious by the teachings of the prior art.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-7 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 5-11 of copending Application No. 10/617847. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Response to Argument

Applicant's arguments September 20, 2007 have been fully considered but they are not persuasive for the reasons set forth below.

Applicant's argument that McNally et al.'s compounds have the ability to inhibit nitric oxide synthase; which is not even a component of MCI-225's known activity; and that, the useful therapeutic activity of MCI-225 is attributed to noradrenaline uptake inhibition, serotonin 5-HT₃ antagonism and serotonin uptake inhibition is persuasive. In view of the new ground(s) of rejection the applicant's arguments are moot.

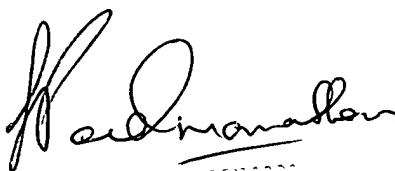
Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan
Supervisor